K081166

510 k Notification: Solica Corp LightStream Laser	4/01/2009

Section 5: 510(k) Summary

APR - 3 2009

I. **General Information:**

Proprietary Name: LightStream Low Level Laser

Common / Usual Name: Infrared Low Level Laser System

Device Classification: 21 CFR 890.5500 Infrared Lamp, Non-Heating

Product Code: NHN

Applicant Name & Address:

Solica Inc.
129 Yorkville Avenue, Suite 300
Toronto, Ontario M5R 1C4
Telephone: (866) 955 -9495
Facsimile: (905) 417 - 4422

Key Contact:

Louie P. Canitano
President, Solica Inc.
e-mail: Lcanitano@solicacorp.com

II. **Device Description**

The LightStream Laser is a handheld, non-invasive, low energy, non thermal infrared therapeutic medical laser. The LightStream Laser System incorporates an AC or battery powered Control Unit and a hand-held laser diode probe with one laser tip and one cluster probe with 5 laser tips. The device incorporate Gallium Aluminum Arsenide (GaAlAs) laser diodes delivering 60mW at the 903 nanometer (nm) wavelength, classifying it under under 21 CFR 890.5500, NHN as non-heating infrared lamp for adjunctive use in pain therapy. The LightStream is a non thermal device and is intended to be for adjunctive use in pain therapy and is not intended to provide therapeutic topical heating.

III. Indication for Use

The LightStream Low Level Laser device is indicated for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice.

IV. Predicate Devices

The LightStream Low Level Laser is substantially equivalent to the Theralase Inc. Theralase TLC-100 (K050342. This devices was cleared for introduction into interstate commerce via the FDA's 510(k) Notification process. The LightStream Low Level Laser has the same intended use and similar technological characteristics as the predicate device.

V. Summary of the Technical Characteristics of the Laser System as Related to the Referenced Predicate Devices.

The LightStream Low Level Laser and the predicate device are non-invasive, low energy, non thermal infrared therapeutic medical infrared lasers as defined in 21 CFR 890.5500, under product code NHN. These devices use infrared diodes laser diodes delivering between 5 -500 Mw at the 930 nanometer (nm) wavelength to emit invisible photonic energy to tissue. The LightStream Low Level Laser and the predicate device has the same intended uses and similar technical and performance characteristics.

VI. Testing

Safety and performance testing was performed on the LightStream Low level Laser. The testing has demonstrated that the device complies with both safety and performance FDA recognized consensus standards that apply to the LightStream Low Level Laser. The LightStream Low level Laser has been tested and complies with the following standards:

General Safety standard:	IEC 60601-1: 2005
EMC	IEC 60601-1-2: 2001
Medical Laser Equipment:	IEC 60601-2-22: 2007
CE Marking Classification:	Medical Device Directive IIb, Certificate No. C10151

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the LightStream Low Level Laser has the equivalent intended uses and similar technical characteristics as the identified predicate device. The LightStream Low Level Laser complies with FDA consensus and internationally accepted standards for therapeutic lasers intended for adjunctive use in pain therapy. The LightStream Low Level Laser performs as intended, meets the requirements for the 21 CFR 890.5500, under product code NHN and does not raise any new questions of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Solica, Inc.
% Ms. Carla Winslow
Controller
129 Yorkville Avenue, Suite 300
Toronto, Ontario M5R 1C4
Canada

Re: K081166

APR - 3 2009

Trade/Device Name: LightStream Low Level Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: NHN
Dated: March 25, 2009
Received: March 30, 2009

Dear Ms. Winslow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081166

Device Name: LightStream Low Level Laser

Indications for Use:

The LightStream Low Level Laser device is intended for adjunct use in the temporary relief of pain associated with knee disorders with standard chiropractic practice.

Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OROver-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081166

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